



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/091,072 06/09/98 TIEMESSEN H 4-100-8288/P

001095
THOMAS HOXIE
NOVARTIS CORPORATION
PATENT AND TRADEMARK DEPT
564 MORRIS AVENUE
SUMMIT NJ 07901-1027

HM12/0315

EXAMINER

JONES, D

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

03/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/091,072

Applicant(s)
Tiemessen

Examiner
Dwayne C. Jones

Group Art Unit
1614



☒ Responsive to communication(s) filed on the amendment filed on 09 Dec 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1614

DETAILED ACTION

Status of Claims

1. Claims 1-8 are pending.
2. Claims 1-8 are rejected.

Response to Arguments

3. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on January 19, 1996. It is noted, however, that applicant has not filed a certified copy of the 9601120.0 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

5. The information disclosure statement filed August 12, 1998 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

Art Unit: 1614

Specification

6. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
 - (b) **Cross-References to Related Applications.**
 - © Statement Regarding Federally Sponsored Research or Development.
 - (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
 - (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
 - (f) Brief Summary of the Invention.
 - (g) Brief Description of the Several Views of the Drawing(s).
 - (h) Detailed Description of the Invention.
 - (I) Claim or Claims (commencing on a separate sheet).
 - (j) Abstract of the Disclosure (commencing on a separate sheet).
 - (k) Drawings.
 - (l) Sequence Listing (see 37 CFR 1.821-1.825).
7. This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1614

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the *treatment* of transplant rejection, autoimmune disease and of inflammatory conditions, does not reasonably provide enablement for the *prevention* of transplant rejection, autoimmune disease and of inflammatory conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The instant application does not provide support guidance to the prevention of transplant rejection, autoimmune disease and of inflammatory conditions. Without such information, one skilled in the art could not predict how this composition could prevent the above-stated ailments or conditions. Accordingly, one skilled in the art would be required to perform undue experimentation to prove how the instant composition is used to prevent such conditions.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1614

11. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bollinger et al. of EP 296,122 A2 possessing a publication date of December 21, 1988 in view of Richter et al. of Ep 589,843 having a publication date of March 30, 1994 and in further view of both Windholz, Editor of The Merck Index, 10th Edition, which has a publication date of July 21, 1986 and Osol, Editor of Remington's Pharmaceutical Sciences, 15th Edition having a publication date of June 11, 1976. Bollinger et al. teach of cyclosporins, in particular the especially preferred Compound No. 1.38 which is [3'-Desoxy-3'-oxo-MeBmt]1-[Val]2-cyclosporin, (as listed on page 10, lined 44-51 and Example H on page 26). Bollinger et al. teach that cyclosporins are useful in reversing resistance to chemotherapy, (see abstract). Bollinger et al. further teach that these cyclosporins can administered parenterally or intravenously, (see page 34, lines 1-12). The prior art reference of Bollinger et al. is silent to incorporation of oleic acid and ethanol. Richter et al. teach that it is well known in the art that since cyclosporins are generally very insoluble in aqueous media, surfactants and emulsifying agents are added in order to solubilize the cyclosporin compounds into an emulsion. Richter et al. teach of adding ethanol to the cyclosporin, (see page 2, lines 33-36 and page 3, 2-6) in addition to adding surfactants selected from C₁₈ unsaturated fatty acid mono-, di- and tri-glycerides, (see page 3, lines 17-25 and lines 37-41). Windholz, Editor of The Merck Index, 10th Edition teach that it is well known in the art that oleic acid is pharmaceutical aid (solvent), (see page 6707 column 1). Osol, Editor of Remington's Pharmaceutical Sciences, 15th Edition, teach that ethanol is a well known solvent in pharmacy, (see pages 1252 and 1253). Since it is taught in the art that [3'-Desoxy-3'-oxo-MeBmt]1-[Val]2-cyclosporin can administered

Art Unit: 1614

parenterally or intravenously and moreover that both oleic acid and ethanol are well established in the pharmaceutical art as pharmaceutical solvents, it would have been obvious to the skilled artisan to combine the above listed components in order to obtain an emulsion of the cyclosporin compound. The determination of solubility is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum pharmaceutical solvents to generate the maximum effect of the drug. Hence, the above-stated references make obvious the instant invention.

Duplicate Claims


12. Claim 6 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 6 attempts to limit claim 5 with the intended use as an oral administration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4634.

Art Unit: 1614

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
March 13, 2000